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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,136	08/18/2006	Anthony John Ujhazy	3869/049 US	1415

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EXAMINER	
BEHRINGER, LUTHER G	

ART UNIT	PAPER NUMBER
3766	

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07/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,136	UJHAZY ET AL.	
	Examiner	Art Unit	
	LUTHER G. BEHRINGER	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the communication received on 06/25/2008 concerning application no. 0/598136 filed on 08/18/2006.

Response to Arguments

2. Applicant's arguments with respect to claim(s) 1 – 15, 31 and 32 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim(s) 1, 2, 4, 5 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320, herein Park)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff) (cited in the last Office Action)**.

Regarding **claim 1,** Park discloses a method of treating sleep disordered breathing comprising the step of applying electrical stimulation of nerves to increase muscle tone of upper airway muscles (Col. 3, Lines 1 – 4), but fails to disclose determining the likelihood of a patient being asleep and applying electrical stimulation based upon that likelihood.

However, Ottenhoff teaches determining the likelihood of a patient being asleep and applying electrical stimulation based upon that likelihood (Col. 5, Lines 32 – 36).

6. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of determining the likelihood of a patient being asleep to achieve optimal stimulation for therapy purposes. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Park to include determining the likelihood of a patient being asleep as taught by Ottenhoff, since doing so would optimize therapy delivery and as a result minimize extraneous therapy delivery thereby conserving battery power.

Regarding **claim 2,** Park in view of Ottenhoff discloses whereby the afferent nerves are stimulated (Park: Abstract). Merriam-Webster online dictionary defines afferent as "conveying impulses towards the central nervous system."

Regarding **claim 4,** Park in view of Ottenhoff discloses whereby the site of electrical stimulation is in the vicinity of the hypoglossal motor nucleus or excitatory afferent nerve pathways leading to this structure (Park: Col. 3, Lines 9 – 14).

Regarding **claim 5,** Park in view of Ottenhoff discloses whereby the electrical stimulation comprises trains of electrical pulses (Park: Col. 3, Lines 56 – 57).

Regarding **claim 14,** Park in view of Ottenhoff discloses whereby stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration (Park: Col. 7, Lines 41 – 44).

7. Claim(s) 3, 6, 13 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320, herein Park)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff)** in view of **Kallok (US 5,158,080)**.

Regarding **claim 3,** Park in view of Ottenhoff fails to disclose whereby the site of electrical stimulation is within or adjacent to the genioglossus muscle.

However, Kallok teaches whereby the site of electrical stimulation is within or adjacent to the genioglossus muscle (Col. 3, Lines 38 – 41).

8. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park in view of Ottenhoff with the teachings of Kallok to provide multiple stimulation locations to improve the efficiency of the sleep apneic therapy method.

Regarding **claim 6,** Park in view of Ottenhoff fails to disclose whereby the train length is approximately 10-30 pulses.

However, Kallok teaches whereby the train length is around 50 pulses (Col. 3, Lines 19 – 20).

9. Kallok discloses the claimed invention except for the specified range of pulses being within 10 – 30 pulses. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the specified range of pulses, since it has been held that where the general

conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Regarding **claim 13 and 32,** Park in view of Ottenhoff fails to disclose whereby stimulation is repeated in accordance with the detected state of the airway.

However, Kallok teaches whereby stimulation is repeated in accordance with the detected state of the airway (Abstract).

10. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park in view of Ottenhoff with the teachings of Kallok to provide a more efficient therapy method for sleep apnea.

11. Claim(s) 7, 10 – 12 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320, herein Park)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff)** in view of **Bowers (US 5,207,230)**.

Regarding **claim 7,** Park in view of Ottenhoff discloses determining the likelihood of a patient being asleep and applying electrical stimulation based upon that likelihood (Col. 5, Lines 32 – 36), but fails to disclose a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles.

However, Bowers teaches a method of treating sleep disordered breathing comprising the step of mechanical stimulation of nerves to increase muscle tone of upper airway muscles (Col. 3, Lines 20 – 23).

12. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park in view of Ottenhoff with the teachings of Bowers to provide an alternative mechanical stimulation of nerves that more efficiently delivers apneic therapy.

Regarding **claim 10,** Park in view of Ottenhoff fails to disclose whereby the mechanical stimulation is periodic.

However, Bowers teaches whereby the mechanical stimulation is periodic (Col. 10, Lines 25 – 30).

13. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park in view of Ottenhoff with the teachings of Bowers to provide periodic mechanical stimulation to more efficiently treat sleep apnea.

Regarding **claim 11,** Park in view of Ottenhoff fails to disclose whereby the period is in the order of several seconds of vibration.

However, Bowers teaches whereby the period is in the order of several seconds of vibration (Col. 10, Lines 25 – 30).

14. It would have been obvious to a person having ordinary skill in the art at the time of the invention to apply the technique of extending the period of mechanical vibration by several seconds as taught by Bowers to improve the sleep apnea method as disclosed by Park in view of Ottenhoff.

Regarding **claim 12,** Park in view of Ottenhoff fails to disclose whereby the mechanical vibration occurs at frequencies in the range of 10-50 Hz.

However, Bowers teaches a low mechanical frequency (i.e., 7 – 8 Hz) (Col. 10, Lines 26 – 27).

15. Bowers discloses the claimed invention except for the specified frequency range of 10 – 50 Hertz. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the specified frequency range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Regarding **claim 33,** Park in view of Ottenhoff in view of Bowers discloses whereby stimulation is carried out in accordance with a model of Cheyne-Stokes Respiration (Park: Col. 7, Lines 41 – 44).

16. Claim(s) 8, 9, 15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Park et al. (US 6,904,320, herein Park)** in view of **Ottenhoff et al. (US 6,251,126, herein Ottenhoff)** in view of **Bowers (US 5,207,230)** and further in view of **Kallok (US 5,158,080)**.

Regarding **claim 8 and 9,** Park in view of Ottenhoff in view of Bowers discloses whereby mechanical stimulation is performed by a piezo electric mechanical element (Col. 3, Lines 20 – 23), but fails to disclose it being implanted at a site in the vicinity of the upper airway.

However, Kallok teaches [an] element implanted at a site in the vicinity of the upper airway or adjacent to the base of the genioglossus muscle (Col. 3, Lines 34 – 41).

17. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park in view of Ottenhoff in view of Bowers with the teachings of Kallok to provide additional implant locations to improve the efficiency of the sleep apnea therapy device.

Regarding **claim 15,** Park in view of Ottenhoff in view of Bowers discloses [an] apparatus for treating respiratory disorders comprising a piezo-electric mechanical element (Bowers Col. 3, Lines 20 – 23), a controller adapted to elicit vibration of the element via an electrical signal (Park Col. 22, Lines 37 – 38), a real time clock for determining time of day, and a position sensor for sensing postural state (Ottenhoff: Col. 5, Lines 32 – 36), but fails to disclose it being adapted for implant within or adjacent the base of genioglossus muscle.

However, Kallok teaches [an] apparatus adapted for implant within or adjacent the base of genioglossus muscle (Col. 3, Lines 38 – 41).

18. It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the disclosure of Park in view of Ottenhoff in view of Bowers with the teachings of Kallok to provide additional implant locations to improve the efficiency of the sleep apnea therapy device.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUTHER G. BEHRINGER whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 8:00 - 5:30; 2nd Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766